IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

FURNIE ODEN, Plaintiff, v. BOSTON SCIENTIFIC CORPORATION., Defendant.	Case No. 2:18-cv-00334-SJF-SIL

MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANT BOSTON SCIENTIFIC CORPORATION'S MOTION TO DISMISS PLAINTIFF'S COMPLAINT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Rules

PRELIMINARY STATEMENT

Defendant Boston Scientific Corporation ("Defendant") moves to dismiss Plaintiff's complaint filed on November 10, 2017 in the above-referenced matter ("Complaint" or "Compl."), asserting that it fails to plead any plausible allegations such that this Court can reasonable infer that its Greenfield™ Vena Cava Filter (the "Greenfield Filter") was defective. Defendant fails to provide any relevant legal or factual support for its arguments made in its motion. Instead, Defendant argues the merit of Plaintiff's claims and unsuccessfully attempts to establish that Plaintiff's allegations are untrue – tactics that are inappropriate in a Rule 12(b)(6) challenge. Worse, Defendant fatally fails to claim that Plaintiff's complaint fails to apprise it of the claims against it, which is the purpose of the pleading standards set by Rules 8 and 12. Plaintiff's complaint sets forth well-pleaded facts that plausibly support Plaintiff's allegations, properly put Defendant on notice of the claims it must defend, and more than satisfies the applicable pleading requirements. Thus, Defendant's motion should be denied in its entirety.

ARGUMENT

I. THE COMPLAINT PROPERLY ALLEGES ALL "PLAUSIBLE" CLAIMS

On a motion to dismiss, the court must take all facts alleged in the complaint as true and draw all reasonable inferences in favor of plaintiff. *See Sweat v. Sheahan*, 235 F.3d 80, 83 (2d. Cir. 2000); *United States v. The Baylor Univ. Med. Ctr.*, 469 F.3d 263, 267 (2d Cir. 2006). The court must also accept all undisputed factual allegations as true and draw all reasonable inferences in the light most favorable to plaintiff. *Robinson v. Malaysia*, 269 F.3d 133, 140 (2d Cir. 2001). Rule 8 requires a short and plain statement of the claim that provides the defendant fair notice of the claim and shows plaintiff is entitled to relief. *Ashcroft v. Iqbal*, 556 U.S. 662, 663 (2009). "[A]

well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable, and that a recovery is very remote and unlikely." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 557 (2007). Rule 8 also calls for "sufficient factual matter, accepted as true, to state a claim to relief that is *plausible* on its face." *Twombly*, 550 U.S. at 570 (emphasis added). "A claim has facial plausibility when the pleaded factual content allows the Court to draw the reasonable inference that the Defendant is liable for the misconduct alleged.". *Iqbal*, 556 U.S. at 678 (citing *Twombly,* 550 U.S. at 556). It should be noted, however, that "detailed factual allegations are not required" *Iqbal*, 556 U.S. at 678. The Supreme Court has reversed Courts for decisions that amount to heightened pleading requirements by insisting plaintiffs "allege 'specific facts' beyond those necessary to state [their] claim and the grounds showing entitlement to relief." *Twombly*, 550 U.S. at 570 (citing *Swirkiewicz v. Sorema N.A.*, 534 U.S. 506, 508 (2002)).

In its motion, Defendant attempts to distract the Court by citing three Middle District of Florida cases that were dismissed based on the Florida District Court's pleading standards regarding "shotgun pleadings." In doing so, Defendant failed to apprise this Court that the Florida cases were not dismissed (without prejudice and with leave to amend) due to lack of sufficiency or plausibility but due to procedural formatting The Eleventh Circuit standard regarding the format of pleadings is not applicable to this Court, and these decisions are neither binding or persuasive. *Cf. Iconix Brand Grp., Inc. v. Bongo Apparel, Inc.*, 2008 U.S. Dist. LEXIS 51791, at *7-9 (S.D.N.Y. July 8, 2008) (complaints are to be upheld "it is not confusing and is not drafted in a manner that gives rise to an inference of bad faith").

A. Plaintiff Sufficiently Pleaded His Strict Liability Claim

Under New York law, a plaintiff may allege that a defendant is strictly liable when its product is defective because of a: (1) design defect, (2) a failure to warn, or (3) defect as a result

of a manufacturing flaw. *Colon v. BIC USA, Inc.*, 199 F. Supp. 2d 53, 63 (S.D.N.Y. 2001); *see also Robinson v. Reed-Prentice Div. of Package Mach. Co.*, 49 N.Y.2d 471, 478-79 (N.Y. 1980). Plaintiff adequately pleaded his allegations to support his claims each of these theories.

1. Manufacturing Defect

To plead a manufacturing defect, the plaintiff must allege that (1) the product was defective due to an error in the manufacturing process and (2) the defect was the proximate cause of plaintiff's injury. *Cowan v. Costco Wholesale Corp.*, No. 15-CV-05552 (PKC), 2017 U.S. Dist. LEXIS 1714, at *9 (E.D.N.Y. Jan. 5, 2017). A defectively manufactured product does not conform in some significant aspect to the intended design, and is flawed because of its construction due to "some mishap in the manufacturing process itself, improper workmanship, or because defective materials were used in construction." *Caprara v. Chrysler Corp.*, 52 N.Y.2d 114, 128-129 (N.Y. 2001). Strict liability is imposed for a manufacturing flaw or defect that renders the product not reasonably safe at the time it leaves the seller's hands and is the proximate cause of injury. *BIC USA, Inc.*, 199 F. Supp. 2d at 85-86; *Robinson v. Reed-Prentice Div. of Package Mach. Co.*, 49 N.Y.2d 471, 479 (N.Y. 1980). Plaintiff has properly pleaded his manufacturing defect claim. Plaintiff alleges that the Greenfield Filter caused the Plaintiff pain and irritation. Compl. ¶¶60-65. Plaintiff alleges that the Defendant's Greenfield Filter was designed and intended to be safe and effective for long-term and permanent use to prevent pulmonary embolism ("PE") and deep vein thrombosis ("DVT"). Compl. ¶¶36-38, 53. However, the Greenfield Filter was not safe and effective for long-term use, and instead, Plaintiff alleges that his injuries which include pain, distress, and need for medical attention are proximately caused by the Greenfield Filter. Compl. ¶¶36-38, 53, 65. Due to Plaintiff's Greenfield Filter still implanted inside him, Plaintiff suffers the risk of IVC filter fracturing, migration, embolization, perforation, heightened susceptibility to

the threat of imminent death, migration, thrombosis, blockage and other life-threatening side effects. *Id.* at ¶¶65-66. Plaintiff alleges that because his filter is now causing these issue, the Greenfield Filter contained defects at the time it left the Defendant's possession which Defendant did not intend for it to contain. *See* Compl. ¶¶ 84-85,109-110. Plaintiff has suffered injuries that he alleges were proximately caused by these defects. *Id.* at ¶¶105, 109-110. Plaintiff's allegations have properly put Defendant on notice of the manufacturing defect claim against it, and thus these allegations survive a Rule 12(b)(6) challenge.

2. Design Defect

. Under New York law," a defectively designed product is one which, at the time it leaves the seller's hands, is in a condition not reasonably contemplated by the ultimate consumer and is unreasonably dangerous for its intended use; that is one whose utility does not outweigh the danger inherent in its introduction into the stream of commerce." *Reed-Prentice Div. of Package Mach. Co.*, 49 N.Y.2d at 479. The question is "whether a reasonable person with knowledge of the potential for injury of the product and of the available alternatives, balancing the product's risks against its utility and costs and against the risks, utility and cost of the alternatives, would have concluded that it should not have been marketed in the condition that it was." *Anderson v. Hedstrom Corp.*, 76 F. Supp. 2d 422, 454-55 (S.D.N.Y. 1999), citing *Cover v. Cohen*, 61 N.Y.2d 261, 266-67 (N.Y. 1984). A manufacturer is held liable regardless of his or his lack of actual knowledge of the condition of the product because he or he is in the superior position to discover any design defects and alter the design before making the product available to the public. *Hedstrom Corp.*, 76 F. Supp. 2d at 454. Plaintiff has properly pleaded his strict liability claim sounding in design defect: Plaintiff alleges that the Defendant's Greenfield Filter was designed and intended to be safe and effective for long-term and permanent use to prevent pulmonary embolism ("PE")

and deep vein thrombosis ("DVT"). Compl. ¶¶36-38, 53. Plaintiff alleges that "[t]he Greenfield Filter was manufactured, designed, marketed, labeled and sold in a defective condition, for use by Plaintiff, FURNIE ODEN'S, physicians and/or healthcare providers, and all other consumers of the product, making the product unreasonably dangerous." Compl. ¶96. Plaintiff further alleges that devices such as the Greenfield Filter are not safe and effective for long-term use, or for the long-term prevention of PEs and DVTs. Compl. ¶¶55-56. Plaintiff alleges that, instead, the Greenfield Filter – as designed – poses serious risk of injury and death, rendering it unreasonably dangerous because the foreseeable risks of harm exceeded its claimed benefits. Compl. ¶69, 97. Plaintiff alleges that the current findings of the filter and the injuries that he has suffered as a result of the Greenfield Filter mirrors other documented issues with long-term use of IVC filters, including Greenfield Filters, such as migration and fracture, and that Plaintiff's allegations sounding in design defect have been well-established and documented. See, e.g., Compl. ¶33-59, 66, with special emphasis on 47 ("FDA warnings stated that IVC filters, in general, are best for short-term use in patients at risk for pulmonary embolism, and implanting doctors are to remove the devices once the risk subsides.")

In New York, a feasible alternative design is one of many non-exclusive factors identified by New York's Court of Appeals in *Voss* for a plaintiff to establish – at trial – that a product is defectively designed. *See* ; *Hedstrom Corp.*, 76 F. Supp. at 458. The Court of Appeals specifically identifies "the availability of a safer design" and "the potential for designing and manufacturing the product so that it is safer but remains functional and reasonably priced," (*Voss v. Black & Decker Mfg. Co*, 59 N.Y.2d 102, 109 (1983)) as two of the primary elements of the ***balancing test*** that a jury should undertake to determine whether the product presents an unreasonable risk of harm. *See also Id.* at 108. The Court of Appeals has reaffirmed that the presentment by plaintiff of

a feasible alternative design is one of the non-exclusive factors to be to be balanced in the prima facie case, "the usefulness of the product to the consumer as designed as compared to a safer design and the functional and monetary cost of using the alternative design." *Hedstrom Corp.*, 76 F. Supp. 2d at 458, citing *Scarangella v. Thomas Built Buses, Inc.*, 93 N.Y.2d 655, 659 (N.Y. 1999). Defendant's reliance upon the decision in *Adamo v. Brown & Williamson Tobacco Corp.* is misplaced: the Court in *Adamo*, in upholding the reversal of a jury's finding post-trial, found that the "alternative design" proposed by plaintiff was not equivalent in function solely because "[t]he function of a cigarette is to give pleasure to a smoker; plaintiffs have identified no other function. Plaintiffs made no attempt to prove that smokers find light cigarettes as satisfying as regular cigarettes--indeed, it is virtually uncontested that they do not." *Adamo v. Brown & Williamson Tobacco Corp.*, 11 N.Y. 3d 545, 551 (N.Y. 2008). The court in *Adamo* acknowledged that a plaintiff need not even make this showing at trial, let alone at the pleading stage. *Id.* at 551 ("It is not necessary in every product liability case that the plaintiff show the safer product is as acceptable to consumers as the one the defendant sold; but such a showing is necessary where, as here, satisfying the consumer is the only function the product has. A cigarette is a different kind of product from the circular saw in *Voss*, whose function was to cut wood, or the molding machine in *Reed-Prentice Div. of Package Mach. Co.* (49 NY2d at 403.), whose function was to melt and form plastic."). Defendant incorrectly asserts that Plaintiff is required to allege a feasible alternative design. Defendant further incorrectly argues that Plaintiff fails to allege a feasible alternative design that would make the product safe. Here, the Greenfield Filter's function is not to give pleasure to its user, and instead is intended to prevent PEs, DVTs, and other blood-clotting issues. Compl. ¶¶29-32; *cf. Adamo* 11 N.Y. 3d at 551. Plaintiff has properly alleged that retrievable filters were viable alternative designs to the long-term or permanent Greenfield Filters.

See id. at ¶¶34-38, 47-52, 54-56, with special concentration on 54. Whether the Greenfield Filter was unreasonably safe so as to be defective is solely for the trier of fact to decide. *See Hedstrom Corp.*, 76 F. Supp. 2d at 424. For these reasons, Plaintiff has sufficiently pleaded his design defect claim, and Defendant's assertions that Plaintiff's allegations are without merit are inappropriate at this stage in the proceedings. Thus, Defendant's arguments in support of the dismissal of Plaintiff's design defect claims fail and should be disregarded entirely.

3. Failure to Warn

"Under New York Law, a plaintiff may recover in strict products liability "when a manufacturer fails to provide adequate warnings regarding the use of its product. This is because a manufacturer has a duty to warn against latent dangers resulting from foreseeable uses of its products of which it knew or should have known. The duty to warn extends to third persons exposed to a foreseeable and unreasonable risk of harm by the failure to warn." *In re Methyl Tertiary Butyl Ether ("MTBE") Prods. Liab. Litig.*, 725 F.3d 65, 123 (2d Cir. 2013). Moreover, "Failure to warn is typically a fact-intensive inquiry for the jury to decide." *BIC USA, Inc.*, 199 F. Supp. 2d at 85. *See Liriano v Hobart Corp.*, 92 N.Y.2d 232, 238 (N.Y.1998) (stating that courts have "squarely held that it is up to the jury to decide whether the manufacturer has, in fact, a duty to warn"). Here, Plaintiff does more than enough to establish the elements of a failure to warn claim.

a. Plaintiff's Allegations State a Sufficient Claim for Failure to Warn

Defendant incorrectly argues that Plaintiff asserts mere conclusory assertions that the warnings for the Greenfield Filter was inadequate without alleging facts as to how said warnings were inadequate. Plaintiff has alleged facts indicating that demonstrate how the warnings and instructions provided with the Greenfield Filter were inadequate. *See Reed v. Pfizer, Inc.*, 839 F. Supp. 2d 571, 577 (E.D.N.Y. 2012). Specifically, Plaintiff alleges:

- The Defendant failed to disclose to physicians, patients, or Plaintiff in detail that its permanent IVC filter, the Greenfield Filters, were subject to breakage, collapse, migration, causing thrombus and/or the appropriate degree of risk of damage to the vena cava wall and other complications. Compl. ¶69.

- Defendant concealed the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the IVC filters, including the Greenfield Filter, as aforesaid. Compl. ¶71.

- Defendant's Greenfield Filter, as designed, researched, developed, manufactured, tested, advertised, promoted, marketed, sold, labeled, and distributed by Defendant, was defective due to the product's inadequate warnings and instructions. Defendant knew, or should have known, and adequately warned that its product created a risk of serious and dangerous side effects, including but not limited to, the migration of the filter to the other parts of the vena cava, heart or other organs, DVT, blood clots, fracture or breakage of the filter and other complications. Compl. ¶116.

- The product was under the exclusive control of Defendant and was unaccompanied by appropriate and adequate warnings regarding the risk of severe and permanent injuries associated with its use, including, but not limited to, the migration of the filter to the other parts of the vena cava, the heart or other organs and perforation of the vena cava or tissue. The warnings given did not accurately reflect the risk, incidence, symptoms, scope or severity of such injuries to the consumer. Compl. ¶117.

These allegations are specific as to the symptoms, scope and severity of the potential side effects, health concerns, and risks. *Pfizer, Inc.*, 839 F. Supp. 2d at 576. Plaintiff also cites specific deficiencies in Defendant's brochures and website for his failure to warn claim.

- "Defendant's product brochure for the IVC filter is different from Defendant's Instructions for Use ("IFU")." Compl. ¶126.

- "The Defendant's product brochure provides limited information possible complications from the use of the IVC filter." Compl. ¶127.

- "Defendant's warnings page on Defendant's website, which possibly reflects the warning given in Defendant's IFUS, Defendant only list general complications and adverse events but fail to warn and state the actual extent of potential injuries caused by Defendant's IVC filters.[1]" Compl. ¶128.

- "Defendant failed to state the full extent of ways in which product was not safe and the numerous serious side effects, of which Defendant had full knowledge and did not accurately or adequately warn." Compl. ¶129.

- "Defendant's warnings and precautions section only cite complications that could arise during immolation of the device." Compl. ¶130.

- "Defendant's warnings and complications nor does it use any strong language that would notify or reasonably be expected to catch the attention of a consumer or Defendant's medical provider." Compl. ¶131.

- "The only section on the webpage that addresses adverse events fails to address the full extent of complications, magnitude of risks involved with the IVC filter. The section cannot be considered a sufficient warning or notice." Compl. ¶132.

Plaintiff alleges with specificity as to Defendant's deficient warnings and instructions, what was missing from these warnings and instructions, why these warnings and instructions were inadequate, and what was needed in these warnings and instructions. *See id.* Defendant intentionally omitted the relevant portions of Plaintiff's complaint to support its specious argument. Plaintiff presented in his complaint a website and brochures made by Defendant were readily available. *See* Compl. ¶¶125, 141, 177, 193. The Second Circuit Court had held that judicial notice "may be taken of the defendants' website for the fact of its publication." *Muller-Paisner v. TIAA*, 289 F. App'x 461, 466, n. 5 (2d Cir. 2008).

[1] http://www.bostonscientific.com/en-US/products/embolic-protection/greenfield-vena-cava-filter/greenfield-vena-cava-filters.html

A plaintiff may recover under strict products liability where the product is defective because the manufacturer failed to provide adequate warnings about the risks and dangers associated with the use, or foreseeable misuse, of its product. *Liriano.*, 92 N.Y.2d at 238. New York courts have contended that "in cases where reasonable minds might disagree as to the extent of plaintiff's knowledge of the hazard, the question is one for the jury." *Passante v Agway Consumer Prods., Inc.*, 12 NY3d 372, 382, 909 N.E.2d 563, 881 N.Y.S.2d 641 (2009). Defendant asks the court to ignore plaintiff's allegations simply by asserting that it believes that its warnings were adequate. Worse, Defendant attempts to claim that these warnings are sufficient due to its brochure, website and IFUs but at the same time asserts that Plaintiff cannot use these same materials for his failure to warn claim. *See* Motion at pp. 13. Defendant claim Plaintiff omits any reference to this language in its materials, but a reading of the Complaint shows that Plaintiff referenced the warnings, precautions and adverse event sections in Defendant's website in his allegations. Defendant has not met its burden of proof on its motion, and thus, its motion should be denied in its entirety.

b. Plaintiff Sufficiently Alleged that Defendant's Inadequate Warnings Caused His Injury

Under New York law, failure to provide adequate warnings regarding the use of a product occurs when warnings and instructions to a plaintiff were inadequate and that this was a substantial factor in causing the plaintiff's injuries. *Fasolas v. Bobcat of N.Y., Inc.*, 150 A.D.3d 147, 157 (2d Dep't 2017). Plaintiff adequately alleges that Defendant's failure to warn about the unreasonable dangers of its products caused Plaintiff's injury. Plaintiff alleges that Defendant's inadequate warnings regarding its Greenfield Filter that were provided to his healthcare providers were relied upon his healthcare providers. Compl. ¶¶136-137, 153. Plaintiff further alleges that, but for the inadequate warnings, Plaintiff never would have proceeded with the implantation of the Greenfield

Filter and/or Plaintiff's physicians never would have implanted the Greenfield Filter into Plaintiff, such that Plaintiff would not have suffered injury. *See* Compl. ¶¶136-137, 153-154. Plaintiff specifically alleges that Defendant had a continuing duty to warn Plaintiff and his physicians of the serious risks of the Greenfield Filter, breached its duty by failing to warn *his* implanting physician of the risks associated with the Greenfield Filter, and this breach directly and proximately caused his injuries. *See* Compl. ¶¶65, 124-125, 152-153, 224. Plaintiff has sufficiently pleaded how Defendant's warnings were inadequate and how said inadequate warnings prompted the use of the Greenfield Filter, causing Plaintiff's subsequent injuries. Therefore, Plaintiff's claim survives.

B. Plaintiff Sufficiently Pleaded His Negligence Claim.

Plaintiff has alleged all the necessary facts to establish his negligence claim. A negligence claim arises with: "(i) the existence of a duty flowing from defendant to plaintiff; (ii) a breach of this duty; (iii) a reasonably close causal connection between the breach and the resulting injury; and (iv) loss, harm or damage." *Packer v. Skid Roe*, 938 F. Supp. 193, 196 (S.D.N.Y. 1996). Defendant cites *Bertini* v. *Smith & Nephew, Inc.* as an example of a case where a claim was dismissed for being "boilerplate allegations. *Bertini* v. *Smith & Nephew, Inc*, No. 13 Civ. 0079 (BMC), 2013 WL 6332684 (E.D.N.Y. 2013). *Bertini* is distinguishable from this present matter: the *Bertini* complaint was dismissed due to the lack of supporting factual allegations to support plaintiff's negligence claim. Here, Plaintiff has alleged relevant, specific facts to support his negligence claims. *Id.*

Defendant, as a designer, manufacturer, and producer of the Greenfield IVC filter which is intended to be implanted within patients including the Plaintiff, had a necessary duty to exercise reasonable care to design a product that was not defective or unreasonably dangerous to

consumers, and duty to warn health care providers and users of the full spectrum of risks, dangers and adverse side effects of implantation of the Greenfield Filter. Compl. ¶¶80-81. Plaintiff alleges that Defendant knew or should have known that its Greenfield Filter was, to the contrary, unreasonably dangerous, and has alleged that it has been established that IVC filters such as the Greenfield Filter are dangerous during long-term or permanent use as Defendant designed, promoted, and intended it to be used. Compl. ¶¶ 34-59, 66-71, 84f, 97. Plaintiff properly alleges that Defendant breached this duty of reasonable care when it manufactured and released its Greenfield Filter to market, and continued to sell it with the knowledge that it did not function as intended and despite Defendant's claims and representations regarding the device's long-term efficacy. Compl. ¶¶82-86. Furthermore, Plaintiff alleged that these defects in the IVC filter caused his subsequent injuries. *Id.* at ¶¶ 64-66, 68, 89-90. Plaintiff has already addressed Defendant's argument regarding his failure to warn and design defect allegations, *supra*, and re-emphasizes here that the Complaint meets the required pleading standards and puts Defendant on notice of its negligence. *Id.* at ¶¶79-89.

C. Plaintiff Has Alleged a Plausible Claim for Warranty

1. Implied Warranty

Under New York law, a manufacturer can be liable for injury caused by the manufacturer's product under theories of negligence, breach of implied warranty, and strict liability in tort. *Plemmons* v. *Steelcase Inc.,* 2007 U.S. Dist. LEXIS 22954, at *15 (S.D.N.Y. 2007) Accordingly, on an implied warranty claim, Plaintiff must allege: "(1) that the product was defectively designed or manufactured; (2) that the defect existed when the manufacturer delivered it to the purchaser or user; and (3) that the defect is the proximate cause of the accident." *Id.* at *3 (internal citations and quotations omitted). Plaintiff must allege that the product was not reasonably fit for the ordinary

purpose for which it was intended, and that the product's lack of fitness was a proximate cause of the Plaintiff's injuries. *Beswick v. Sun Pharm. Indus., Ltd.*, No. 10-CV-357A, 2011 U.S. Dist. LEXIS 45378, at *19 (W.D.N.Y. Mar. 4, 2011). While strict liability relies on the risk/utility negligence standard of conduct, breach of warranty asks *only* if the product is fit for the ordinary purpose such products are intended for. *See People v. McNair*, 87 N.Y.2d 772, 774 (2006). The latter cause of action asks only if the product not minimally safe for it expected purpose, disregarding the feasibility of alternative design or reasonableness in marketing in the unsafe condition. *Id.*

Plaintiff alleges that the Greenfield Filter with which he was implanted was not merchantable nor reasonably suited or fit for the ordinary purpose for which it was and is being used. Compl. at ¶¶100-101. Plaintiff has also sufficiently alleged that the Greenfield Filter with which he was implanted was not reasonably fit for its intended use. Compl. at ¶¶150-151, 155-173. Plaintiff alleged that the Greenfield Filter was not fit for its ordinary purpose or for its intended use at the time it left Defendant's control. Compl. at ¶¶94-95, 107, 113, 136. Plaintiff has also alleged that the product's defects caused his injuries. *See* Compl. ¶¶155-173. Therefore, Plaintiff's breach of implied warranty claims are adequately plead.

2. Express Warranty

To maintain a viable breach of express warranty claim against a seller of goods, a plaintiff "must allege that the actionable representation was the 'basis of the bargain.'" *Williams v. Dow Chemical Co.*, 255 F. Supp. 2d 219, 230 (S.D.N.Y. 2003) (internal citations omitted). New York Uniform Commercial Code (U.C.C.) § 2-313(1)(b) provides that "any description of the goods which is made part of the basis of the bargain creates an express warranty [by the seller] that the

goods shall conform to the description." *Fagan v. Amerisource Bergen Corp.*, 356 F. Supp. 2d 198, 217 (E.D.N.Y. 2004).

In the *Sun Pharm. Indus., Ltd.*, the Western District Court ruled that a complaint pleading that the defendants in the case expressly promised that its product was safe through its sales and marketing campaigns, and that the plaintiff relied on that information when he started taking the product leading to his subsequent injuries and damages was sufficient facts to establish a claim for break of express warranty. 2011 U.S. Dist. LEXIS 45378 at *19. A claim of breach of express warranty is essentially required for a tort action based on fraud or misrepresentation -- *i.e.*, a belief in the truth of the representations made in the express warranty and a change of position in reliance on that belief. *CBS, Inc. v. Ziff-Davis Pub. Co.*, 75 N.Y.2d 496, 502 (N.Y. 1990). A seller's warranty whether express or implied extends to any natural person if it is reasonable to expect that such person may use, consume or be affected by the goods and who is injured in person by breach of the warranty. *Id.* A seller may not exclude or limit the operation of this section. N.Y. U.C.C. Law § 2-318.

Plaintiff alleges that Defendant used multiple sources in its marketing and sale campaign to make representations and warranties regarding the purported long-term safety and efficacy of its Greenfield Filter, including but not limited to its website, IFUs, Brochures and other materials. Compl. ¶¶193-198, 202, 204. Plaintiff's allegations cite to the specific language used by Defendant in its representations and warranties regarding its Greenfield Filter, including its "Proven Stability", "Established Filter Performance" and "Filter Design Promotes Clot Lysis". Compl. ¶¶141-153. Plaintiff alleges that his Greenfield Filter did not function as represented or as it was expressly and impliedly warranted to do by Defendant. *Id.* at ¶141-149. Plaintiff has adequately

asserted his allegations of injury resulting from Defendant's breach of its warranties. *See* Compl. ¶¶64, 138, 155, 166. Thus, Plaintiff has sufficiently pleaded his breach of express warranty claims.

D. Plaintiff Has a Valid Claim Under The GBL

For claims under New York's General Business Obligations law, Plaintiff must allege that (1) the act, practice or advertisement was consumer-oriented; (2) it was misleading in a material respect; and (3) the plaintiff was injured as a result of the act, practice or advertisement. *Pelman v. McDonald's Corp.*, 237 F. Supp. 2d 512, 525 (S.D.N.Y. 2003); *see also City of N.Y. v. Smokes-Spirits.com, Inc.*, 12 N.Y.3d 616, 621 (2009) Plaintiff has sufficiently pleaded these claims.

Plaintiff alleges throughout his complaint that Defendant's brochures, advertisements, websites, and marketing documents for its Greenfield Filter were used for advertising purposes – putting Defendant on notice that its advertising was consumer-oriented. Compl. ¶¶177-186, 194-205, 214-218. Plaintiff alleges that Defendant's brochures and other marketing materials are misleading and omit important and material information regarding its Greenfield Filter and made misleading claims regarding the efficacy of its device for long-term use. *See id.* Plaintiff alleges that Defendant's misleading materials and advertisements caused Plaintiff and his medical providers to believe that the device was safe and effective for long term use, and induced them to use the product and implant it in Plaintiff. *Id.* at ¶¶230-232. As result of the long-term implantation, Plaintiff suffered injuries caused by the IVC Filter rendered defective due to, *inter alia*, Defendant's material and misleading representations, omissions, and inadequate warnings regarding the Greenfield Filter. *Id.* at ¶ 23. Thus, Plaintiff's GBL claims are properly pleaded.

E. The Complaint Adequately Alleges Punitive Damages

Defendant argues that Plaintiffs' punitive damages claim must be dismissed because his other claims fail. As shown *supra*, Defendant is incorrect. Moreover, Defendant implies that

Plaintiff must prove that Defendant "acted with malice or such a conscious and deliberate disregard of the interest of others that the conduct may be called willful or wanton" - - in his initial pleadings. *See* Motion at pp. 22-23. To the contrary, Plaintiff must make this showing at trial, not at this stage in the proceedings.

Moreover, Plaintiff sufficiently alleges facts to support his prayer for punitive damages against Defendant. Plaintiff has alleged that Defendant acted intentionally to fraudulently misrepresent material information about the IVC Filters and concealed this information such that Plaintiff, his physicians, and the public would not be able to find this information for themselves. Compl. ¶¶ 186-187, 203-209, 216-222. The laws of New York, which governs, allows recovery of punitive damages in product liability cases like this one. *See Brink's, Inc. v. New York*, 717 F.2d 700, 705 (2d Cir. 1983). Pursuant to New York law, the decision to award punitive damages and their amount are questions which primarily reside in the jury's discretion. *Racich v. Celotex Corp.*, 887 F.2d 393, 397 (2d Cir. 1989). Even summary judgment is inappropriate where "a reasonable jury could return a verdict for the nonmoving party." *Sribnyj v. New York,* No. 85 CIV. 2770, 1990 U.S. Dist. LEXIS 7140, 1990 WL 83477, *3 (S.D.N.Y. June 12, 1990). Following this precedent, the Court may not determine whether punitive damages should be stricken until all evidence is heard and the claims are evaluated on the merits, therefore a motion to strike punitive damages is premature and improper based upon ripeness.

II. PLAINTIFF'S FRAUD BASED CLAIMS SHOULD NOT BE DISMISSED

A. Plaintiff Has Met the Rule 9(b) Pleading Requirements

Rule 9(b) requires that a plaintiff plead with specificity the circumstances of the fraud and plead the defendant's required mental state. *See Loreley Fin. (Jersey) No. 3 Ltd. v. Wells Fargo Sec., LLC*, 797 F.3d 160, 171 (2d Cir. 2015). While Rule 9(b) requires that the circumstances

constituting fraud be stated with particularity, at the pleadings stage, the alleged fraud need only be plausible based on the complaint; it need not be more likely than other possibilities. *Loreley Fin. (Jersey) No. 3 Ltd*, 797 F.3d at 171. In determining the adequacy of a plaintiff's fraud pleadings under these various requirements, the Court must view the alleged facts in their totality, not in isolation. *Id.* As always at the Rule 12(b)(6) stage, the Court must credit all non-conclusory factual allegations in the complaint and draw all reasonable inferences in plaintiff's favor. *Id.* Moreover, recent decisions have held that circumstances arise in which a flexible approach to complainants have been applied under Rule 9(b) to preserve claims that may otherwise fail for ripeness at an early stage. *See, e.g.*, *Grubbs v. Kanneganti,* 565 F.3d 180 (5th Cir. 2009).

To satisfy the Rule 9(b) standard for pleading fraud, a plaintiff's complaint must: (1) detail the events giving rise to the fraud, such as the statement/omission that is alleged to be fraudulent, the identity of the speaker, the location of the fraud, and the reason the statement is fraudulent; and (2) allege facts "that give rise to a strong inference of fraudulent intent." *Loreley Fin. (Jersey) No. 3 Ltd.* 797 F.3d at 171. Under New York law, the elements of fraud are: (1) a material misrepresentation or omission of a fact, (2) knowledge of that fact's falsity, (3) an intent to induce reliance, (4) justifiable reliance by the plaintiff, and (5) damages. *Loreley Fin. (Jersey) No. 3 Ltd* 797 F.3d at 170, citing *Eurycleia Partners, LP v. Seward & Kissel, LLP*, 12 N.Y.3d 553, 559, 910 N.E.2d 976, 883 N.Y.S.2d 147 (2009). The complaint must "(1) detail the statements or omissions that the plaintiff contends are fraudulent, (2) identify the speaker, (3) state where and when the statements (or omissions) were made, and (4) explain why the statements or omissions are fraudulent." *Loreley Fin. (Jersey) No. 3 Ltd,* 797 F.3d at 171

Plaintiff has met the Rule 9(b) pleading standard for his fraud-based claims. Plaintiff alleges that Defendant fraudulently provided material and incorrect information and statements

regarding its IVC Filters by: expressly stating that its IVC Filters were having "Trusted Performance, Timeless Design" and "Proven Stability", "Established Filter Performance" and "Filter Design Promotes Clot Lysis". Compl. ¶¶141-153. Defendant represented that its IVC filters were safe and effective for its intended and reasonably foreseeable use. Compl. ¶¶177-180, 194-197. Plaintiff alleges that Defendant made fraudulent omissions regarding its IVC Filters by: purposely not warning of complications involving its IVC Filters of which they were aware; providing no warnings or indication of possible complications from the use of its IVC filters; failing to warn and state the actual extent of potential injuries caused by its IVC filters; failing to state the full extent of ways in which its IVC Filters were not safe; and failing to state that the IVC Filters and had numerous serious side effects, each of which Defendant had full knowledge. *Id.* at ¶¶186-187, 203-209, 216-222.

Plaintiff alleges that Defendant had full and actual knowledge that its statements and omissions were false and fraudulent, and the warnings and instructions that Defendant did provide with the IVC Filters were incomplete and wholly inadequate. *Id.* at ¶¶177-187, 194-204, 216-218. Defendant had sole access to the information that would show that its material statements and omissions were false and knew that plaintiff, providers, and the public would have no way of knowing the truth. *Id.* at ¶¶187-188, 206, 221.

Defendant, its officers, directors, employees, agents, representatives; and other persons acting on its behalf and its agents made these fraudulent statements and omissions. *Id.* at ¶¶16, 186, 207, 216. Defendant's fraudulent statements and omissions were made in Defendant's website, brochures, IFUs, labels that accompanied the IVC filters, advertisements, marketing documents, and other materials and literature. *Id.* at ¶¶175-185, 193-204, 213-216. Plaintiff alleges that Defendant made these fraudulent statements and omissions to induce and mislead Plaintiff,

Plaintiff's physicians, hospitals and healthcare providers into reliance and cause them to purchase, prescribe and/or dispense and/or use or continue the use of Defendant's IVC Filters, all in furtherance of Defendant's own financial interest. *Id.* at ¶¶207, 209, 217, 219. Plaintiff has alleged the date and time that Defendant's made these statements to the Plaintiff and/or his physicians or medical care providers: on or about the date of his implant. *Id.* at ¶¶59-63. Similarly, Plaintiff's negligent misrepresentations allegations are also sufficiently pleaded with specificity as to the relevant facts surrounding this claim (*i.e.*, who, what, where, when, why). *Id.* at ¶¶212-224.

Defendant knew and expected that recipients of its false information and omissions would rely on the information and act upon that information. *Id.* at ¶¶186, 190, 209, 210, 223. Plaintiff sufficiently alleges that Plaintiff, Plaintiff's physicians, hospitals and healthcare providers justifiably and reasonably relied upon Defendant's fraudulent statements and omissions. *Id.* Plaintiff, Plaintiff's physicians, hospitals and healthcare providers' justifiable reliance on Defendant's fraudulent statements and omissions was the cause of Plaintiff's injuries. *Id.* Thus, Plaintiff's fraud and negligent misrepresentation claims meet the Rule 9(b) specificity requirement.

III. LEAVE TO AMEND

Should the Court decide to dismiss all or part of the Complaint, Plaintiff respectfully requests leave to amend his Complaint in this matter. Rule 15 intends for leave to amend to be freely granted, absent surprise or prejudice resulting from any delay. *See, e.g., Feldman v. Finkelstein & Partners, LLP*, 76 A.D.3d 703, 705, 907 N.Y.S.2d 313 (NY App. Div. 2d Dep't 2010). Plaintiff submits that there would be no surprise or prejudice to Defendant should this Court decide to dismiss part or all of Plaintiff's Complaint and grant leave to amend. Moreover, the prejudice to Plaintiff should the Court dismiss part of all of the Complaint without leave to

amend would be great: the issues here are far too complex to suggest that the denial of leave to amend under these circumstances would be either fair or appropriate.

CONCLUSION

Defendant's motion should be denied in its entirety. Plaintiff has sufficiently pleaded his allegations to survive a Rule 12(b)(6) challenge, and further has articulated his fraud-based allegations with the specificity required under Rule 9(b). Defendant's arguments to the contrary are unavailing, not convincing, and must be disregarded. In the alternative, Plaintiff respectfully submits that leave to amend should be freely given to Plaintiff should the Court grant Defendant's motion in whole or in part.

Date: February 7, 2018

Respectfully submitted,
MARC J. BERN & PARTNERS LLP

By: */s/ Debra J. Humphrey* .
Debra J. Humphrey, Esq. (DH5457)
60 E. 42nd St., Suite 950
New York, New York 10165
Tel: (212) 702-5000
Fax: (212) 818-1064
Attorney for Plaintiff

CERTIFICATE OF SERVICE

I hereby certify that on February 7, 2018, I served the foregoing Memorandum of Law in Support of Plaintiff's Opposition to Boston Scientific Corporation's Motion to Dismiss and the Declaration of Debra J. Humphrey in support thereto via FedEx on the following parties:

Angela Vicari, Esq.
ARNOLD & PORTER KAYE SCHOLER LLP
250 West 55th Street
New York, New York 10019
Attorney for Defendant Boston Scientific Corporation

/s/ Debra J. Humphrey